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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,414	05/30/2001	Anton-Lewis Usala	35626/234825	7087

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EXAMINER

GUPTA, ANISH

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/870,414

Applicant(s)

USALA, ANTON-LEWIS

Examiner

Anish Gupta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-55 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5-2-05.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. The amendment filed, 5-2-05, has been acknowledged. Claims 54-55 were added.

Claims 1-55 are pending in this application.

#### ***Claim Rejections - 35 USC § 103/Double Patenting***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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2. Claims 1-53 remain and new claims 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usala (WO00/02999) in view of Miller et al. in further view of Davis or Pickart et al. for the reason set forth in the previous office action and the reasons set forth below.

3. Claims 1-53 remain and new claims 54-55 are are rejected under 35 U.S.C. 103(a) as being unpatentable over Usala (US 6231881) in view of Miller et al. in further view of Davis or Pickart et al. for the reason set forth in the previous office action under and the reasons set forth below.

4. Claims 1-29-31-42, 46-48, and 50-51 remain and claims 54-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of U.S. Patent No. 6,261,587 in view of Miller and in further view of Davis or Pickart et al.

For all rejections, Applicants have made similar arguments.

Note that claim 53 was inadvertently omitted from the rejection in the previous office but has been incorporated herein. Note that the issue of diabetic related foot ulcers was addressed in the previous office action, dated 11-04-03, on page 6.

The claims are drawn to a method of treating an ulcer by the administration of a hydrogel matrix comprising gelatin and a long chain carbohydrate.

For both rejections Applicants argue that the secondary reference does not provide motivation for the addition of a hydrogel. While the reference, on page 761, "contains a single sentence that addresses granulation tissue and reepithelialization, the reference only mentions those effects as a consequence of surgical debridement of necrotic tissue." The only motivation provided by the sentence is to utilize tissue debridement as a means for

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preparing for granulation tissue and reepithelialization. Further, statements in with regards to antibiotics and growth factors are not wholly accurate in the rejection. Miller reference teaches that a “moist environment” promotes the desired reepithelialization. Miller is only speculative with respect to the addition of benzyol peroxide that it “might” stimulate granulation of tissue. With respect to growth factors, “reference does not state that growth factors lead to tissue granulation. . . . There is clearly no express teaching that would lead to granulation of tissue and ultimate treatment of an ulcer.” The reference of Davis and Pickart et al. does not resolve the issues with Miller since they only describe the cascade of events involved in wound healing and note that formation of blood vessels is only one aspect of granulation of tissue formation. Granulation tissue formation involves other processes, such as fibroblast activity and reepithelialization. “There is no suggest in either refernce that stimulation of blood vessel formation alone will automatically trigger the remaining wound healing process (i.e. fibroblast activity or reepithelialization) that are necessary for tissue granulation.”

Applicants arguments filed, 5-2-05, have been fully considered but have not been found persuasive.

Applicants claims are drawn to “a method of treating an ulcer.” Treatment is usually defined as management and care of a patient for the purpose of combating disease or disorder. Thus a method of treating an ulcer can be defined as management and care of a patient for the purpose of combating an ulcer. Any beneficial effect that the management or care may achieve would be inclusive of treatment.

Applicant’s focus of page 761 of Miller is misplaced. The sentence “[n]eototic tissue and callus must be completely excised to provide a clean ulcer base in preparation of granulation tissue and reepithelialization.” Thus, the reference implies that that granulation

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and reepithelialization of the ulcer is desired. Assuming arguendo, that moisture is the key to reepithelialization in Miller, this yet again illustrative of the desire of the reference to encourage granulation and reepithelialization of the tissue. While Applicants are correct that "the reference does not state that growth factor lead to tissue granulation." The reference does state growth factors "attract fibroblast and other cells involved in early phase of wound healing." Thus, the reference does imply the addition of agents for the promotion of wound healing. Usala et al. Discloses hydrogel that encourage vascularization, one would be motivated to use such hydrogel to encourage the desired granulation and vascularization of tissue. There would be an expectation of success since the Miller states that, for the treatment of ulcers, agents that encourage wound healing can be added. Simple vascularization would meet the limitation of treatment since it is a beneficial affect in granulation of tissue formation. As applicants have pointed out, Davis and Pickart teach that blood vessel formation is an aspect of granulation tissue formation (see page 11-12 of the arguments). Thus, one would be motivated to, at the very least, encourage blood vessel formation to achieved granulation using they hydrogels of Usala et al.

The rejections are maintained.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened

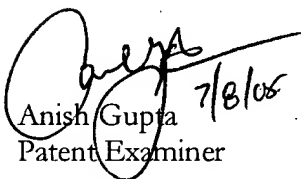
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statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Anish Gupta  
Patent Examiner